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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,991

04/13/2006

Lital Alfonta

54000711US

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03/26/2007

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.

P O BOX 458

ALAMEDA, CA 94501

EXAMINER

GEBREYESUS, KAGNEW H

ART UNIT

PAPER NUMBER

1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/575,991

Applicant(s)

ALFONTA ET AL.

Examiner

Kagnew H. Gebreyesus

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1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 33-44 is/are pending in the application.
- 4a) Of the above claim(s) 1-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31, 33-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/06/06&12/26/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse dated February 21, 2007 to the Office Action mailed on December 15, 2006 is acknowledged. Claims 27, 28 and 31 are amended. Claim 32 has been cancelled. Furthermore, Applicants present a table to indicate support for new or amended claims. Claims 31, 33-44 are present for examination.

Applicants further traverse the restriction requirement because Applicants contend that there was no lack of unity under PCT Rule 13 for the groups as presented in the ISA report stated in the equivalent Application. Applicant's argument has been considered but not found persuasive. The invention first claimed in the instant application is a generic claim drawn to a composition comprising an O-RS that preferentially aminoacylates an O-tRNA with a redox-active amino acid. As stated in the written opinion, Schultz et al in WO200286075-A2 teach compositions comprising an O-RS that preferentially aminoacylate an O-tRNA with a variety of unnatural amino acids including redox active amino acids. Where prior art anticipates or makes obvious the invention first disclosed in an application, unity of invention is lacking under PCT Rule 13.1 therefore, the ISA report and Written Opinion in PCT/US04/34089 are correct. Applicants request to rejoin group III comprising claims 27-30 with Group IV.

The examiner has required restriction Group III and IV. Applicants are reminded that where the product claims in Group IV are found allowable, withdrawn process claims (Group III) that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §

821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Priority

Priority is acknowledged for this application, which claims the benefit of PCT/US04/34089 filed on October 13, 2004, and U.S. Provisional Application No. 60/511532, filed on October 14, 2003.

Information Disclosure Statement

The information disclosure statement filed on October 6, 2006 and December 26, 2006 for which a copy of the patent publication has been submitted in this application has been considered as shown by the Examiners signature next to each reference.

Oath/Declaration

The oath or declaration submitted on April 13, 2006 has been reviewed and is in compliance with 37 CFR 1.63.

Claim Objections

Claim 40 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 40 does not further limit claim 39 which, depends on claim 31, drawn to a composition comprising a protein wherein the protein comprises a redox active unnatural amino acid selected from the group consisting of: a 3,4-dihydroxy-L-phenylalanine (DHP), a 3,4,5-trihydroxy-L-phenylalanine, a 3-nitro-tyrosine, a 4-nitro-phenylalanine, and a 3-thiol-tyrosine.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 33 recites the limitation "at least 75% identical to that of a wild type therapeutic protein, a diagnostic protein, an industrial enzyme or a portion thereof ". There is insufficient antecedent basis for this limitation in the claim because there is no disclosure of a sequence for any wild type therapeutic protein, diagnostic protein or industrial enzyme to compare the claimed protein composition.

Claim 42 is objected to for the recitation: "improved oxidation". It is not clear what Applicants intend to encompass by this term i.e. the metes and bounds of this term is unclear. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 31, 33-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Schultz et al (US 7, 045,337 B2) as evidenced by Rodriguez et al. (The Reciprocal

Exclusion by L-Dopa (3,4-hydroxy-L-phenylalanine and L-Tyrosine of their incorporation as Single Units into a Soluble Rat Brain Protein, Biochemistry Journal (1975) 149, 115-121).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 31, 33-44 are anticipated because Schultz et al teach incorporating various unnatural amino acids into proteins of interest. Page 8 column 2, line 46-67, page 17, column 1, line 46-48, page 33 under the title "Compositions that include Proteins with Unnatural Amino Acids" and through out the specification teach composition comprising a wide variety of proteins including therapeutic proteins, diagnostic proteins and industrial proteins comprising one or more unnatural amino acids (see for e.g. pages 35-36). In one aspect of Schultz et al's invention, the protein comprises the unnatural redox-active amino acid 3,4-hydroxy-L-phenylalanine (DHP) (see figure 17, page 28). Furthermore Schultz et al in fig. 29 show additional unnatural redox active amino acids (e.g. S64, S41). Paragraph [0318] of Schultz et al expressing myoglobin comprising a desired unnatural amino acid (claims 39, 40). [0245] teaches pharmaceutical compositions comprising a protein comprising a desired unnatural amino acid. [0048] teaches one or more unnatural amino acids can be incorporated in

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the protein (claim 38). Therefore claims 31, 33-43 drawn to compositions comprising a protein that comprises one or more unnatural amino acid including the redox-active amino acids 3,4-hydroxy-L-phenylalanine (DHP) are anticipated by Schultz et al. Rodriguez et al teach that 3,4-hydroxy-L-phenylalanine is incorporated into a protein in such a way that it excludes the incorporation of L-tyrosine thus providing evidence for the protein composition taught by Schultz et al. The embodiments in claims 41, 42 and 44 are inherent to the redox-active unnatural amino acid incorporated into the protein. Therefore claims 31, 33-44 are anticipated by or are obvious over the teachings of Schultz et al.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31, 33, 34, 39-44 are rejected under 35 U.S.C. 102(a) as being anticipated by Alfonta et al. (Site Specific Incorporation of a Redox-Active Amino Acid into Proteins. 2003. Journal of American Chemical Society. 2003, 125, 14662-14663). Alfonta et al teach incorporation of 3,4-hydroxy-L-phenylalanine into the surface exposed C-terminal hexahistidine tagged mutant sperm whale myoglobin. Said modified protein comprising the DHP was expressed to a level of 1mg/L in phosphate buffer (see figure 2), thus reads on claim 34. Claim 33 is also anticipated because there is no

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sequence disclosure thus reads on any protein. The embodiments in claims 41, 42 and 44 are inherent properties of the redox-active unnatural amino acid incorporated into the protein. Therefore claims 31, 33, 34, 39-44 are anticipated by or are obvious over the teachings of Alfonta et al.

Claims 31, 33, 39, ⁴⁰41-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Rodriguez et al. (The Reciprocal Exclusion by L-Dopa (3,4-hydroxy-L-phenylalanine and L-Tyrosine of their incorporation as Single Units into a Soluble Rat Brain Protein, Biochemistry Journal (1975) 149, 115-121). Rodriguez et al teach that 3,4-hydroxy-L-phenylalanine is incorporated into a protein in such a way that it excludes the incorporation of L-tyrosine. Claims 33 and 39 are included in this rejection because ~~the Rodriguezes~~ because identification of DHP containing proteins were performed using carboxypeptidase fragments thus within the limitation of claims 33 and 39. The embodiments in claims ⁴⁰41, 42 and 44 are inherent properties of a redox-active unnatural amino acid. Thus the disclosure by Rodriguez et al anticipates claim 31 by teaching a protein containing DHP.

Relevant reference(s): A New Redox Cofactor in Eukaryotic Enzymes: 6-Hydroxydopa at the Active Site of Bovine Serum Amine Oxidase. 1990. Janes et al. Science. Vol. 248, No. 4958 (May, 1990), pp. 981-987.

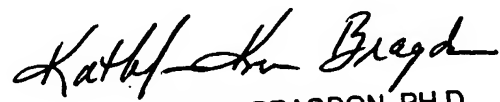
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnaw H. Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5: 30pm.

KB
3/19/07

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kagnew Gebreyesus PhD.
KG
March 14, 2007


KATHLEEN KERR BRAGDON, PH.D.
SUPERVISORY PATENT EXAMINER